

REMARKS

I. The Office Action

Claims 11-74 are currently pending in the application. Claims 36-46 are under examination, and claims 11-35 and 47-74 are withdrawn from consideration for being directed to non-elected subject matter. Claims 38 and 39 were rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking written description. Claims 36-46 were rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of Weimar et al., *Exp. Hematology*, 26(9), 885-894 (1998) (“Weimar”); Kollet et al., *Blood*, 97(10), 3283-3291 (2001) (“Kollet”); International Patent Publication No. WO 02/50263 (“Forbes”); Devine et al., *Exp. Hematology*, 29, 244-255 (2001) (“Devine”); and Shi et al., *Haematologia*, 92, 897-904 (2007) (“Shi”). Reconsideration of these rejections is respectfully requested.

II. Amendments to the Claims

Claim 36 has been amended to recite that the stem cells are exposed to hepatocyte growth factor (HGF) or an active portion thereof alone. Claim 75 has been added and recites that stem cells are exposed to a composition consisting essentially of hepatocyte growth factor (HGF) or an active portion thereof. Support for the amendment and for new claim 75 is found in the specification at, e.g., page 7, lines 15-19; page 33, lines 9-13; and page 35, line 27, through page 36, line 20. Claims 38 and 39 have been canceled. No new matter has been added by way of the amendments.

III. The Rejection Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

The Office asserted that the amendment to claim 36 reciting that the stem cells are exposed to hepatocyte growth factor (HGF) “in the absence of stem cell factor (SCF)” introduced new matter to the application. Specifically, the Office asserted that the subject matter encompassed by “in the absence of SCF” is not supported by the originally filed application. The Office acknowledged that the specification discloses stem cells exposed to HGF alone, HGF in the presence of SCF, or HGF in the presence of IL-6, and suggested that the claims be amended to recite that stem cells are exposed to HGF alone or HGF in the presence of IL-6.

Claim 36 has been amended to recite that the stem cells are exposed to hepatocyte growth factor (HGF) or an active portion thereof alone, which the Examiner has acknowledged to be supported by a written description. Claims 38 and 39 have been canceled. New claim 75, reciting the semi-closed transitional term “consisting essentially of,” has been added. Use of the transitional term “consisting essentially of” excludes methods involving use of compounds other than HGF that materially affect the basic and novel characteristics of the claimed invention. See M.P.E.P. § 2111.03. The written description requirement ensures that the applicant had possession of the claimed subject matter as of the filing date upon which reliance is placed (M.P.E.P. § 2161.01(I)), and “[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations....” M.P.E.P. § 2163(I). As noted in M.P.E.P. § 2111.03, “[t]he transitional phrases ‘comprising,’ ‘consisting essentially of’ and ‘consisting of’ define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.” Thus, the transitional phrases address what unrecited limitations are embraced by a claim and the written description requirement mandates a supportive written description of all recited, but not unrecited, limitations of a claim. This interpretation comports with common sense; if this interpretation were incorrect, all open-ended “comprising” claims would require description of everything known to man, as nothing is excluded from such a claim. Beyond the transitional phrase, new claim 75 is closely modeled on pending claim 36 and is amply supported by written description in the passages cited above in Section II of this paper. Thus, the rejection under 35 U.S.C. § 112, first paragraph, has been overcome-in-part and rendered moot-in-part and should be withdrawn.

IV. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn.

The Office rejected claims 36-46 under Section 103(a) for assertedly being obvious in view of Weimar, taken with Kollet, Forbes, Devine, and Shi. The rejection of claims 36-46 is respectfully traversed for the reasons set forth below.

The Office asserted that it would have been obvious to isolate CXCR4-positive cells from the HGF and IL-6-treated stem cells in Weimar in view of the disclosure of Kollet, which the Office characterizes as teaching that IL-6 increases CXCR4 expression,

migration and homing potential of stem cells. As amended, claim 36 provides for exposing stem cells to HGF alone and isolating stem cells having CXCR4 levels above a predetermined threshold. New claim 75 provides for exposing stem cells to a composition consisting essentially of HGF and isolating stem cells having CXCR4 levels above a predetermined threshold. In view of the semi-closed transitional phrase of claim 75, this claim excludes from its scope an unrecited compound that would materially alter the basic and novel characteristics of the subject matter, such as a compound that would allow the Office to impose an art-based rejection. For purposes of traversing this art-based rejection, a composition consisting essentially of HGF is effectively equivalent to reciting “HGF alone,” and it is in terms of “HGF alone” that the majority of the traversal will be phrased. None of the cited references, considered alone or in combination, discloses or suggests that treatment of stem cells with HGF alone has an effect on CXCR4 levels. Weimar does not teach exposing stem cells to HGF alone (or to compositions consisting essentially of HGF) and isolating stem cells having CXCR4 levels above a predetermined threshold. Thus, the Office has not established that the cited art discloses or suggests each element of any rejected claim, and the rejection should be withdrawn.

One of ordinary skill would not have had a reasonable expectation of success in modifying the teachings of Weimar to expose stem cells to HGF alone and isolating stem cells having CXCR4 levels above a predetermined threshold. SCF was reported in the art to be significantly more potent than HGF as a survival factor, and addition of HGF did not enhance survival of treated cells. See Weimar, paragraph bridging pages 889-890. In addition, Weimar teaches that incubation of stem cells with HGF alone failed to induce colony formation, and no synergistic effect was observed on colony formation when HGF was combined with IL-6. (Weimar, page 888, first full paragraph; Table 2.) The cited art does not recognize HGF and SCF or IL-6 to be equivalent with respect to their effects on stem cells and, given the advantages of SCF disclosed in Weimar, one of ordinary skill would not have been motivated to modify the teachings of Kollet to omit IL-6 or SCF. Furthermore, one of ordinary skill would not have had a reasonable expectation of success in substituting HGF alone for IL-6 or SCF; the results of substituting HGF alone for HGF in the presence of IL-6 or SCF would not have been predictable in view of the Weimar teachings that HGF does not promote proliferation or survival to the same degree as IL-6 or SCF. Finally, Weimar is

silent in regard to exposing stem cells to HGF alone and isolating stem cells having CXCR4 levels above a predetermined threshold. Thus, a person of ordinary skill in the art would not have had a reasonable expectation of success in performing the claimed methods and the rejection should be withdrawn.

Forbes, Devine, and Shi are cited as purportedly disclosing or rendering obvious various features recited in the dependent claims; the references, however, do not remedy the deficiencies of the Weimar and Kollet references. The disclosure in Forbes of HGF as an anti-fibrolytic agent expressible by stem cells may have led one of skill to alter the source of HGF, but would not lead an ordinarily skilled artisan to otherwise modify the teachings of Weimar. Devine merely reports that mesenchymal and hematopoietic stem cells have similar homing properties. The Shi reference was published in 2007 and, therefore, is not available as art against the pending claims.

For the reasons set forth above, the cited references do not render obvious the subject matter of claims 36, 37, and 40-46 and would not render obvious the subject matter of new claim 75. None of the references, considered alone or in any combination, teaches or suggests a method of generating stem cells suitable for transplantation comprising exposing collected stem cells to HGF or an active portion thereof alone (or to compositions consisting essentially of HGF), as claimed. Accordingly, Applicants respectfully request withdrawal of the Section 103(a) rejection and submit that a corresponding rejection of new claim 75 would be improper.

V. Conclusion

Applicants submit that the pending application is in condition for allowance, and the Examiner is respectfully requested to pass this application to issue. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions that might be efficiently resolved in that manner.

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Respectfully submitted,

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